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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,429	08/07/2006	Norihiro Nishimoto	053466-0417	6508

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FOLEY AND LARDNER LLP
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WASHINGTON, DC 20007

EXAMINER

SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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09/07/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,429	Applicant(s) NISHIMOTO ET AL.	
	Examiner Lorraine Spector	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29,31,38,39,41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 29-33 and 35-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/3/10</u> . | 6) <input type="checkbox"/> Other: _____ |

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/3/10 has been entered.

In the submission filed 5/3/10, applicants traverse the finality of the previous office action. This traversal is moot, in view of the filing of the RCE under 37 CFR § 1.114. Applicants are advised for future reference that the finality of an office action may be traversed by filing a petition under 37 CFR 1.181. See MPEP § 1002.02(c).

Claims 29, 31, 38-39 and 41-42 are under consideration.

The rejections under 35 USC §102 and §103 over the Giles-Komar and Samid references are withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 34-36, 38, 39 and 41-42 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Okuda et al., U.S. Patent Number 7,521,052, formerly rejected under 35 USC §102(a) over U.S. PG-PUB Number 2006/0251653, which has now matured to the above

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patent. Because the ground of rejection remains the same, and the addition of the rejection under 102(e) is due to the maturation of the application to a patent and has been fully addressed by applicants in their reply, this is not considered to be a new ground of rejection.

Okuda teaches a pharmaceutical composition for the treatment of IL-6 related diseases, comprising an IL-6 antagonist (claim 1) which may be an antibody (Ab) to the IL-6 receptor (claim 6), monoclonal (claim 7), recombinant (claim 10), PM-1 antibody (claim 11, Chimeric, humanized or "human type", humanized PM-1 (claim 13-14), and may be used in the treatment of vasculitis (claim 15). Paragraphs [0002], [0006] and others also specifically contemplate treatment. Accordingly, the claims are anticipated by Okuda et al.

Okuda's effective filing date is 4/28/2004.

Applicants argue that Okuda cannot be applied under either 102(a) or (e), as it merits a priority date of 4/28/2004, whereas the instant application claims foreign priority to application JP 2003-423517, filed 12/19/2003. This argument has been fully considered but is not deemed persuasive because no certified English translation of the Japanese document has been submitted, such that foreign priority is not perfected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 31 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Okuda et al., in view of Hirohata et al., Clinical Immunology and Immunopathology 66:225, 1993.

The teachings of the primary reference are discussed above. Although they teach treatment of vasculitis, they do not specifically mention the form of vasculitis known as polyarteritis nodosa, as claimed in Claim 31.

Hirohata et al. teach that polyarteritis nodosa is associated with marked elevation of CSF IL-6 activity in parallel with CNS disease activity, and showed elevation of serum IL-6 in association with systemic systems.

Accordingly, in view of Hirohata's teaching, the person of ordinary skill in the art would have been motivated to treat polyarteritis nodosa with IL-6 inhibitors such as those taught by the primary reference. Accordingly, the invention as claimed is *prima facie* obvious.

Applicant's only applicable argument pertaining to this ground of rejection is that "Even though Hirohata describes the relationship between elevated IL-6, polyarteritis nodosa and vasculitis, it does not follow that IL-6 is causative of the disease, or that the disease could be treated by an antagonist to IL-6 or, more specifically, by an antibody against the IL-6 receptor." This argument has been fully considered but is not deemed persuasive because applicant is arguing the reference individually, rather than the combination in which it was cited. Further, applicants have failed to establish why the person of ordinary skill in the art would not see the teachings of Hirohata as pointing to the treatment of polyarteritis nodosa by inhibition of IL-6. Such is the most parsimonious explanation of Hirohata's teaching, and it is the practice in the art to always look first to the most parsimonious explanation; this concept is known as "Occam's razor". Accordingly, it remains that the invention as claimed is *prima facie* obvious over Okuda et al. in view of Hirohata et al.

Conclusion

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday from 8:00 A.M. to 4:30 P.M., and Tuesday, Thursday and Friday, 8:00 A.M. to 2:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Dr. Gary Nickol, at telephone number 571-272-0835.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
/Lorraine Spector/
Primary Examiner
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